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SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521			MYERS, CARLA J	
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1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,675	Applicant(s) SQUIRES ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/20/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 138-145 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 138-145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/3/06; 10/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 11, 2005 has been entered.

Claims 138-145 are pending and have been examined herein.

Information Disclosure Statement

2. The information disclosure statement filed in this application on 10/11/2005 fails to include a concise statement of the relevance of the following non-English language reference listed, as required under 37 CFR § 1.98(a)(3): Ozhin et al (1961); Prokefiew (1983); Solsberry (1966); Wintzer (1982). The above items of information have not been considered by the examiner. Additionally, the Pursel et al (1978) and Van Munster (1999; Sex Determination by Interferometry) references have not been considered because a copy of these references was not provided (the record provided consisted of only the citation to Pursel et al). The Waggoner et al (1990), Reiling (1997), Rutter (1993), Shackelford (1995) references have not been considered because these references are not readable. The Recktenwald reference has been considered only for the single paragraph overview of "Cell Separation Methods and Applications" on the page entitled

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“about the book.” The other items of information that are otherwise in compliance with the provisions of 37 CFR §1.97-1.98 have been considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 138-145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not appear to provide support for the claimed methods of establishing an equine artificial insemination sample containing at least some sperm that are capable of fertilizing at least one egg within a female equine “at success levels selected from the group consisting of at least 90%, at least 81%, at least 75%, at least 65%, at least 60%, at least 57%, at least 40%, at least 35%, at least 30% of a typical unsorted insemination dosage.”

The originally filed specification includes claim 97 which is directed to a method of “practically producing an equine mammal” wherein the method includes the step of “fertilizing at least one equine egg within said female species of said equine mammal at success levels selected from the group consisting of at least 90%, at least 81%, at least 75%, at least 65%, at least 60%, at least 57%, at least 40%, at least 35%, at least 30%.”

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Thereby, the originally filed claim provides support for the concept of an artificial insemination sample that can be used to achieve the recited success rates. The originally filed claim does not provide support for the concept that insemination sample contains some unstated proportion of sperm that have the property of being capable of achieving the recited success rates. That is, the present claims define the success rates that can be achieved with of "at least some of said viable equine sperm" in the artificial insemination sample. This concept is not supported by the originally filed claim in which the method of artificial insemination is defined in terms of including a step of fertilizing an egg with an artificial insemination sample at success rates of at least 90%, 81%, 75%, 65%, 60%, 57%, 40%, 35% or 30%.

Further, the specification as originally filed appears to provide support only for the concept of a method which achieves success levels "statistically comparable to the typical artificial insemination dosage wherein the success levels are at least 90%, 81%, 75%, 65%, 60%, 57%, 40%, 35% or 30% using a low number of equine sperm relative to a typical artificial insemination dosage (see original claim 97). Note that claim 97 does not recite the use of sex-sorted sperm. Additionally, page 9 of the specification discloses methods in which mares were artificially insemination one time with unsorted 25×10^6 sperm and a "pregnancy rate of 57%" was achieved. It is stated that there was no difference between mares bred using artificial insemination samples of 25×10^6 sperm versus 5×10^6 sperm. Pages 32-33 of the specification set forth the results obtained using unsorted semen samples of 500×10^6 in 20 ml, 25×10^6 in 1ml, 5×10^6 in 1 ml, and 5×10^6 in .2ml to achieve overall pregnancy rates of 90%, 57%, 30% and

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40%. At pages 10 and 35-40, the specification discloses methods in which pregnancy rates of 50% were achieved using 25×10^6 sperm sorted at rates of 900 live sperm collected per second. It is stated (page 39) that "(t)he pregnancy rate at day 16 following insemination of 25×10^6 sexed spermatozoa (40%) was not statistically different ($P > 0.1$) than that of mares in Experiment 1 inseminated with 25×10^6 non-sorted progressively motile spermatozoa (57%)." these teachings in the specification and in the original claims do not, however, appear to provide support for methods of artificial insemination of equine with sex sorted semen in which the success levels are defined in terms of a comparison with that achieved with a typical unsorted insemination dosage and in which fertilization occurs "at success levels selected from the group consisting of at least 90%, at least 81%, at least 75%, at least 65%, at least 60%, at least 57%, at least 40%, at least 35%, at least 30% of a typical unsorted insemination dosage."

Additionally, it is noted that while originally filed claim 97 recited a method of producing an equine mammal wherein the method includes the step of fertilizing at least one equine egg within said female species of said equine mammal at success levels selected from the group consisting of at least 90%, at least 81%, at least 75%, at least 65%, at least 60%, at least 57%, at least 40%, at least 35%, at least 30% using a low number of equine sperm relative to a typical artificial insemination dosage, the specification as originally filed did not provide proper antecedent basis for this subject matter. If Applicant intends to claim the subject matter of original claim 97, then the specification must be amended to provide basis for this subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 138-140, and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (U.S. Patent No. 5,985,216) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath (Theriogenology. April 1997, 795-800; cited in the IDS) .

Rens teaches a method of high speed flow cytometry for sorting sperm. In the method of Rens (see columns 4-6), a sample of sperm is obtained from a male mammal, the sperm is stained with Hoeschst 33342 dye in order to distinguish between

viable and nonviable sperm (column 5, lines 4-10), the sperm are sorted in a high speed flow cytometer using a nozzle that forms a stable droplet containing each individual sperm cell (column 2, lines 23-32), the sperm are sorted according to their sex characteristics and isolated populations of X- and Y-chromosome bearing sperm are collected. Approximately 50% of the sperm were viable and the sorting was performed at sampling rates of 500 sperm/sec and 2000 sperm/sec (see column 6). Further, the nozzle allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). Rens exemplifies using the claimed sorting method using rabbit, bull, mouse and human sperm (columns 4-7) and states that the sorting method can be used with any mammalian sperm (column 4, lines 38-42). Rens does not specifically exemplify applying the sorting method to equine sperm.

However, Wilhelm teaches the use of equine sperm for the purpose of artificial insemination. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rens to the sorting of equine sperm in order to have provided an effective means for distinguishing between and collecting populations of X- and Y-chromosome bearing sperm useful for artificially inseminating equine.

Secondly, Rens does not specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm

teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the artificial insemination sample that is obtained using the modified method of Rens in which the equine sperm is collected into a media containing egg yolk and skim milk that the sample contains at least one viable sperm cell that is capable of fertilizing at least one equine egg at a level of at least 30% that of a typical unsorted equine artificial insemination dosage.

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With respect to claim 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claim 143, Rens does not specify the pressure used to operate the high speed cell sorter. However, methods for sorting equine sperm using high speed cell sorters were well known in the art at the time the invention was made. To determine the optimum conditions for performing a method step is well within the skill of the art. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

With respect to claims 144 and 145, Rens teaches that 4 to 5 million sorted sperm were used to inseminate dairy cows, but does not teach the quantity and volume of sperm in equine artificial insemination samples. Additionally, Rath (page 796) teaches the use of .2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of .2 ml. Rath teaches that approximately 3.5 to 4×10^5 sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the

art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique.

Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed the rejection over Rens in view of Wilhelm and Rath by arguing that Rens does not teach the sampling rates of the present invention. The response states that a sampling rate is distinct from a sorting rate in that a sampling rate refers to the number of analysis events, whereas a sorting rate refers to the actual number of sperm sorted per second. Applicants assert that in the method of

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Rens the elliptical nozzle is capable of orienting in excess of 60% of sperm for sorting and thereby only about 60% of the sample sperm are properly oriented for sorting. It is further asserted that Rens does not discuss the particular parameters required to achieve the sorted rates. Thereby, Applicants conclude that Rens "cannot support an obviousness concern with respect to the sorting rates recited in the present claims." This argument has been fully considered but is not persuasive. While it is agreed that Rens does not specify the sampling rate, the information provided by Rens does indicate that the method of Rens and the sorting apparatus of Rens can be used to achieve sampling rates equivalent to that of the claimed invention. The present claims recite a method in which the separation rates are "at least nine hundred viable equine sperm cells per second." Rens (col. 6) exemplifies methods using sampling rates of 2000 sperm/second and teaches that the nozzle allowed for sample rates of up to at least 15,000 sperm/second. If the proper orientation is achieved for 60% of the sperm (note that Rens teaches that the correct orientation is achieved in excess of 60% of sperm), then the rates of sorting in the method of Rens would be at least 1200 sorts/sec (for sampling rates of 2000sperm/sec) or 9000 sorts/sec (for sampling rates of 15,000 sperm/sec). Further, the present specification relies on the apparatus' disclosed in the prior art in order to achieve the sampling rates set forth in the claims. Applicants have not disclosed any means for increasing the sorting rate of sperm about that disclosed by Rens.

The response argues that Rens does not provide any data on rates of successful fertilization achieved using the sorted sperm. Applicants state that "this leaves open the

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possibility that an artificial insemination sample produced by the technique of Rens may not be able to achieve the success rates recited by the present claims – Rens simply does not provide sufficient data to make this determination.” However, if Rens does not provide sufficient information to conclude that fertilization can be achieved at rates similar to the claimed rates, then it is not possible for Applicant to conclude that the method of Rens does not achieve fertilization rates comparable to that of the claimed invention. Applicants have not provided any evidence to substantiate their assertion that the method of Rens may not be able to achieve the fertilization rates of the claimed invention. Applicant’s speculate that “(i)t is entirely possible that the technique of Rens may perhaps compromise the fertilizing ability of the sperm it sorts.” However, Applicants do not provide any sound scientific arguments or evidence to support such a contention. Further, Applicants do not point to any particular limitations that are recited in the claims which distinguish the claims over the sorting method of Rens and which would thereby result in the asserted difference in technique. That is, the response does not clarify what technique utilized by Rens and specifically excluded by the present claims compromises the fertility of the sperm.

Applicants argue that the achievement of the success levels of the present invention at the sort rates of the claims would have been unexpected. This argument has been fully considered but is not persuasive because mere allegation in the absence of factual evidence cannot be used to establish unexpected results. As set forth in the MPEP 716.02, the burden is placed on Applicant to establish that “the differences in results are in fact unexpected and unobvious and of both statistical and practical

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significance.” *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992).

There must be a clear nexus between the asserted unexpected results and the method steps that allow for the unexpected results. Further, the claims must be commensurate in scope with the aspects of the invention which allow for the asserted unexpected results. The present response argues that equine sperm are delicate and flow cytometry techniques may contribute to stresses that adversely affect sperm cells. It is also stated that to achieve the claimed invention requires more than optimizing quantities and volumes and that “it would require some technique to counteract the detrimental effects of high speed sorting on equine sperm cells, which are precisely the techniques taught by the present invention. Therefore, with respect to the references cited and the ordinary artisan skill in the art, only the present case teaches techniques that for the first time permit high speed flow cytometry to become a viable method to separate sperm in equine applications.” However, the response does not specifically address which techniques recited in the present claims distinguish the claimed method over that of Rens and account for the ability of the claimed method to counteract the detrimental effects of high speed sorting. In the absence of such, it appears that applicants are arguing limitations that are not recited in the claims. Regarding the high speed sorting method, the claims recite only the technique of separating droplets at a rate of at least nine hundred viable sperm cells per second. As discussed above, these sorting rates are suggested by the method of Rens. Further, the claims do not recite any particular properties of the sorting apparatus which would distinguish the claimed sorting technique over that of Rens. The data set forth in the specification establish only

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the ability to sort equine sperm at rates of 900 sperm/sec. No evidence has been provided to establish the ability to sort equine sperm at rates greater than 900 viable sperm/sec and to achieve unexpectedly improved rates of fertilization. The response does not establish a clear nexus between the claims as they are broadly written and any asserted unexpected results. For instance, there is no showing that sorting equine sperm at any rate of 900 or above (1000, 2000, 10,000, 20,000 sperm/sec etc) using any apparatus, any sheath fluid, any collection device, any quantity of sperm etc can be used to achieve fertilization rates of at least 90% that of a typical unsorted insemination dosage. It has also not been established that it is unexpected that one could obtain by high speed sorting an artificial insemination sample containing at least some viable equine sperm cells which have a fertilization level of at least 30% that of a typical unsorted equine artificial insemination dosage.

The specification does not provide any clear teachings as to which aspects of the claimed invention are essential and account for the asserted unexpected results. Throughout the specification there are statements indicating that a particular feature may be important alone or in combination in determining the success of the artificial insemination method. However, the statements are vague and are not accompanied by any factual data. For instance, at page 6 the specification states that "the solutions proposed may to some degree involve a combination of factors which, when thoroughly statistically studied, will be shown to be necessary either in isolation or in combination with other factors. Such a determination is further compounded by the fact that the results themselves vary by species and may be difficult to ascertain due to the fact that

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testing and statistical sampling on a large enough data base is not likely to be worth the effort at the initial stages." Regarding high speed flow sorting, the specification (page 18) states that "(w)ith advances it is anticipated that the percent of sperm that are oriented properly as the droplets pass the laser can increase, resulting in increased sorting rates from 100 live sperm/s of each sex to rates between 1000 and 1500 live sperm/s of each sex at ~90%." However, the specification does not provide any specific details as to the advances which allow for this improved sorting and the response does not point to any particular limitations recited in the claims which allow for the increased sorting rate while maintaining the ability of the sperm to fertilize oocytes at the claimed success rates. Accordingly, for the reasons set forth above, Applicants assertion of unexpected results is not persuasive because the assertion is not accompanied by any factual evidence and there is no showing of a clear nexus between the asserted unexpected results and the claims as they are broadly written.

5. Claim 141 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Wilhelm and Rath and further in view of Catt (cited in the IDS of January 29, 2001).

The teachings of Rens, Wilhelm and Rath are presented above. The combined references do not teach establishing a sheath fluid which contains a HEPES buffered medium. Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page 252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability

and motility of sperm. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens in view of Wilhelm so as to have used a HEPES-buffered medium for establishing a sheath fluid because Catt teaches that this is a suitable dilution medium for sperm and thereby using HEPES-buffered medium as the sheath fluid would have achieved the benefit of ensuring the viability and motility of the sperm.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed this rejection for the same reasons as stated above. Accordingly, the response to those arguments as presented above apply equally to the present grounds of rejection.

6. Claims 138-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (U.S. Patent No. 6,149,867) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath.

It is noted that the '867 patent and the present application share a common inventor and assignee. However, the inventorship and assignee of the '867 patent is distinct from that of the present application.

Seidel teaches a method of high speed flow cytometry for sorting equine sperm. The method of Seidel comprises obtaining a sample of sperm from a male mammal, staining the sperm in order to distinguish between viable and nonviable sperm, sorting the sperm using a high speed flow cytometer having a nozzle that forms a stable droplet containing each individual sperm cell wherein the sperm are sorted according to their sex characteristics and isolating populations of X- and Y-chromosome bearing sperm

are collected (see column 6). Seidel (column 7) teaches sorting at rates of greater than 500 sorts per second and up to 1000 to 1200 sorts per second. The reference also teaches operating the flow cytometer at pressures of about 50 lbs per square inch (column 7). Seidel teaches that when sorting equine sperm, the preferred sheath fluid contains HEPES buffer (column 9).

Seidel teaches that "it has been known to place an initial collector fluid (17) in the bottom of the container to collect the cells so that they do not hit the bottom of the container" (column 10). Seidel states that the collector fluid "may serve to minimize chemical stresses upon the cells. In one regard, since it may be important to provide a nutrient to the cells both before and after sorting, the collector fluid (17) may be selected so as to provide a coordinated level of nutrient so that the levels are balanced both before and after sorting" (column 10). The reference teaches that an egg yolk solution may be used as the collection fluid and that the collection fluid may be chosen so that it is similar to the starting fluid environment or any other fluid environment used in the method (column 11). It is also stated that that the levels of egg yolk may be varied "as those skilled in the art readily understand" (column 11).

Seidel does not specifically teach using a collection fluid that contains skim milk. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender

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effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the artificial insemination sample that is obtained using the modified method of Seidel in which the sperm is collected into a media containing egg yolk and skim milk that the sample contains at least one viable sperm cell that is capable of fertilizing at least one equine egg at a level of at least 30% that of a typical unsorted equine artificial insemination dosage.

With respect to claims 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, as taught by Seidel, it would have

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been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claims 144 and 145, Seidel (column 12) teaches using a low dose of sperm for artificial insemination and teaches concentrating bovine sperm to a level of 3-5 million sperm cells per ml (column 13), but does not teach the quantity and volume of sperm in an equine artificial insemination sample. Additionally, Rath (page 796) teaches the use of .2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of .2 ml. Rath teaches that approximately 3.5 to 4×10^5 sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the

original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique.

Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

In the response, Applicants state that the 103 rejection has been overcome by the filing of a 131 declaration to remove the '867 patent as prior art.

However, the 131 declaration of George Seidel, filed February 20, 2006 is not sufficient to antedate the '867 patent. In particular, the 131 declaration does not establish that the acts relied upon to establish the date prior to the reference were carried out in this country or in a NAFTA country or WTO member country. See MPEP 715.

Further, 131 declarations to overcome a rejection of the claims must be made by the inventor or inventors of the subject matter of the rejected claims. However, the 131 declaration filed February 20, 2006 has not been signed by each of the inventors of the present application. As stated in the MPEP at 715.04, "(a)n affidavit or declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. For example, one of two joint inventors is accepted where it is

shown that one of the joint inventors is the sole inventor of the claim or claims under rejection.” In the present situation, it has not been established that the inventor George Seidel alone is the sole inventor of the **claims** under rejection.

Lastly, the scope of the declaration is not commensurate with the scope of the claimed invention. The declaration states that the declarant “was in possession of the subject matter of claim 138 (g), of the Present application.” In particular, the declaration points to Exhibit C as showing that Dr. Seidel was in possession of a method in which sperm are sorted at rates of greater than about 500 sorts per second and that sorting may be performed at rates in the thousands and twelve hundred ranges. However, a 1.131 declaration must establish possession of either the whole invention claimed or something falling within the claim. Where the differences between the claimed invention and the disclosure of the references are so small as to render the claims obvious over the reference, an affidavit or declaration under 37 CFR 1.131 is required to show no more than the reference shows. In the present situation, the ‘867 patent is not limited to teaching only step (g) of present claim 138. Accordingly, the declaration is not sufficient because the declaration does not establish that applicants were in possession of each of the method steps of the claimed invention or each of the method steps set forth in the ‘867 patent, prior to the effective filing date of the ‘867 patent.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION:

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 138-145 are provisionally rejected on the ground of nonstatutory obviousness-

type double patenting as being unpatentable over claims 1, 5-12, 16, 17, 19-29, 165-

167, 169, 170, 172-183 and 185 of copending Application No. 09/582,809 in view of

Rath and Wilhelm. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the present claims and the claims of '809

are both drawn to methods for producing a nonhuman mammal wherein the methods

comprise collecting sperm cells from a male, establishing a cell source which supplies

sperm cells, sorting sperm cells so as to separate the sperm cells according to sex,

inserting a portion of the sperm cells into a female and fertilizing at least one egg of said

female. The present claims differ from the claims of '809 in that they are limited to

methods for establishing an equine artificial insemination sample, whereas the methods

of '809 are broadly drawn to methods for establishing an artificial insemination sample

containing sperm cells from any nonhuman mammal. However, the recitation of

nonhuman mammals necessarily includes equine mammals and claims 25 and 177 of

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'809 specifically recites the use of equine sperm. Further, the claims of '809 do not recite the step of establishing a skim milk solution into which the droplets are separated based on a sex characteristic. specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Additionally, Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326). Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of '809 so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 138-145 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-141 of U.S. Patent Application No. 10/081,955 in view of Rath and Wilhelm. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '809 are both drawn to methods for producing a nonhuman mammal wherein the methods comprise collecting sperm cells from a male, establishing a cell source which supplies sperm cells, sorting sperm cells so as to separate the sperm cells according to sex, inserting a portion of the sperm cells into a female and fertilizing at least one egg of said female. The present claims differ from the claims of '809 in that they are limited to methods for establishing an equine artificial insemination sample, whereas the methods of '809 are broadly drawn to methods for establishing an artificial insemination sample containing sperm cells from any nonhuman mammal. However, the recitation of nonhuman mammals necessarily includes equine mammals and claims 25 and 177 of '809 specifically recites the use of equine sperm. Further, the claims of '809 do not recite the step of establishing a skim milk solution into which the droplets are separated based on a sex characteristic. specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution.

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However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Additionally, Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326). Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of '809 so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-

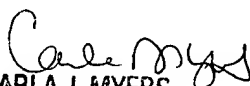
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0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
April 24, 2006


CARLA J. MYERS
PRIMARY EXAMINER